Hey Jane

CLINICAL WHITE PAPER

Safe, effective, and in-demand: An asynchronous telehealth abortion model for a new era of care

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Synopsis

Access to safe, high-quality abortion care has been a persistent issue in the United States. This issue predates the current access crisis created by the 2022 *Dobbs v. Jackson* ruling that overturned *Roe v. Wade*, which protected an individual's constitutional right to choose to have an abortion before "viability".

Telemedicine medication abortion (teleMAB) provides a solution that directly increases access to safe, high-quality care while addressing the increased demand for care that is currently straining the healthcare system. A teleMAB care model provides abortion pills by mail under the virtual supervision and support of a medical provider. This enhances privacy, eliminates the need to find an in-person clinic appointment, and avoids delays with scheduling, waiting for, and traveling to that appointment. TeleMAB is responsive to patient demand for a virtual care model, which has been heightened by the COVID-19 pandemic (Shaver, 2022).

Hey Jane offers a primarily asynchronous* teleMAB care model that does not require a patient to have a synchronous appointment with a clinician. Research shows that an asynchronous care model is just as safe, effective, and patient-accepted as a synchronous model (Raymond et al., 2019). The asynchronous teleMAB care model significantly expands access by removing multiple barriers that patients face when seeking an abortion. Hey Jane's asynchronous teleMAB care model is patient-centered and adaptive, giving patients the choice to have a virtual face-to-face or phone encounter with a member of the clinical care team.

***Asynchronous telehealth**, also known as "store-and-forward," is communication between parties that is not live. In asynchronous models of care, patient information is forwarded (sent), and then stored (in a HIPPA compliant software system) until the provider has the opportunity to review.

Abortion care with Hey Jane follows evidence-based care and clinical practice guidelines set forth by the National Abortion Federation (NAF), a leading authority in abortion care. Since its inception, Hey Jane has demonstrated a track record of providing safe and high-quality care. Hey Jane's quality data on patient care outcomes definitively demonstrates that its model of care is safe, effective, and highly acceptable to patients. External validation of Hey Jane's safety, efficacy, and acceptance data has been provided as part of a research partnership with Advancing New Standards in Reproductive Health (ANSIRH), a program within the UCSF Bixby Center for Global Reproductive Health and part of UCSF's Department of Obstetrics, Gynecology & Reproductive Sciences.

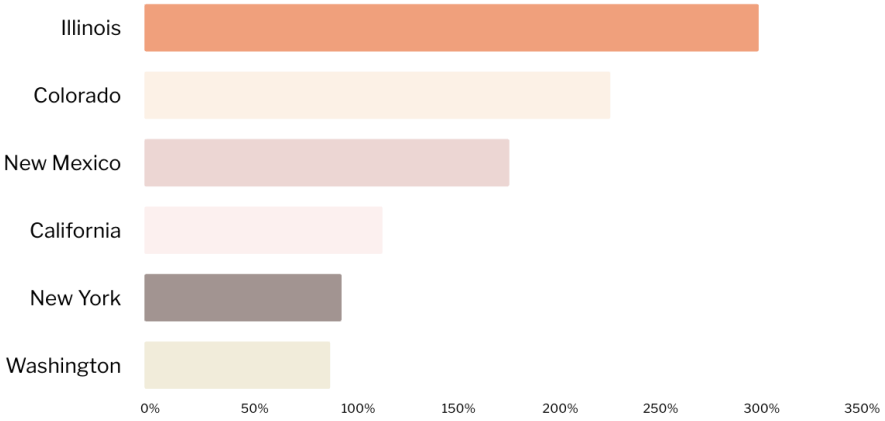
Introduction

Historically, people seeking abortion care within the healthcare system were limited to in-person surgical or procedural methods in outpatient clinics, physician's offices, or hospital settings. In 2000, the FDA approved mifepristone for use with misoprostol to terminate a pregnancy with high efficacy and minimal side effects (Center for Drug Evaluation and Research, 2000). The availability of an FDA-approved medication regimen as an alternative to procedural methods to terminate a pregnancy significantly increased access to abortions. Approximately 5.6 million people in the U.S. have used medication to induce an abortion since mifepristone was approved (FDA, 2022). Medication abortion is now the most common form of abortion, representing more than half of all U.S. abortions up to 10 weeks of gestation (Sagar et al., 2023).

Despite widespread mifepristone availability since 2000, access to safe, high-quality, and patient-accepted abortion care is still limited in many states and regions in the U.S. There is a common misconception that abortion care is available through primary care physicians (PCPs) or obstetrician-gynecologists (OB-GYNs). But the number of providers offering abortion services has always been insufficient. That was true even before *Dobbs v. Jackson* overturned *Roe v. Wade* in 2022, erasing the constitutional right to choose to have an abortion before "viability." Only 14% of OB-GYNs in the U.S. provided abortions (Stulberg et al., 2011) and only 3% of PCPs provided abortion services (Patel et al., 2020). Access issues are exacerbated by strained clinics in urban areas as well as insufficient number of clinics in rural areas. *Dobbs* has exacerbated the provider shortages in restrictive states and overburdened clinics in others.

Other barriers to abortion care include travel, work obligations, caregiving responsibilities, healthcare system navigation difficulties, limited clinic options, and costs (Jerman et al., 2017). These barriers can result in delays in care, adverse mental health effects, and increased cost and complexity (Jerman et al., 2017). Abortion access issues disproportionately impact patients of lower socioeconomic status and those who identify as Black, Hispanic, Asian, or Pacific Islander (Increasing Access to Abortion, 2020).

Figure 1: Hey Jane patient volume increases post-*Dobbs*
(July 2022- May 2023)



Source: Hey Jane internal data

Figure 1: During the timeframe of July 1, 2022 to May 31, 2023, following the *Dobbs* decision, Hey Jane's patient volume increased substantially. The highest increase was in Illinois, with a 301% increase in patient volume.

Post-*Dobbs*, more individuals have been seeking, and often traveling, for telemedicine abortion. This is particularly prevalent in states that border a restrictive state, including Illinois, Colorado, and New Mexico (Hey Jane, 2023). Surges in volume post-*Dobbs* have put tremendous pressure on the remaining in-person clinics, resulting in longer appointment wait times and unaccommodated patients. In some instances, extended wait times for appointments result in patients missing the gestational age cutoff for medication abortion or first-trimester procedural abortion. These factors influence how people think about teleMAB care as a tool for expanding access and meeting patient demands.

Multiple high-quality studies conducted during the COVID-19 pandemic found the effectiveness and safety rates of teleMAB without ultrasonography or pelvic examination were similar to in-person screening (Upadhyay et al., 2022) and avoided delays in care (Koenig et al., 2023).

Asynchronous telemedicine abortion care model

Hey Jane's teleMAB care model enhances safety and efficacy by allowing patients and clinicians to decide if they prefer a virtual video or audio clinical encounter. Most patients opt to communicate asynchronously via a HIPAA-compliant application. This allows patients to continuously connect to the clinical care team throughout their care journey. This innovative care model enables pairing of concierge-level clinical accessibility with highly specialized quality medical care to patients. Patients can connect via an anonymous forum, and they have 24/7 access to educational and emotional support materials.

Hey Jane's tech-enabled teleMAB care model addresses both physical and emotional health needs in a real-time way that is unparalleled in the industry. It is responsive to what patients want: an intuitive, accessible platform to receive comprehensive, high-quality, safe abortion care. This high patient satisfaction with our care model is evidenced by Hey Jane's Net

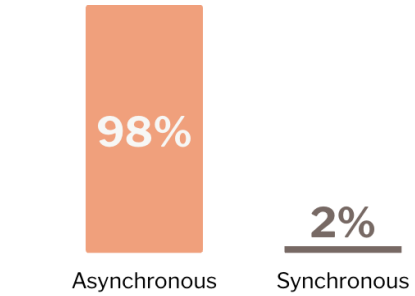
Promoter Score* (NPS) for 2022, which was 92, approximately 10x higher than the healthcare industry average.

> ***Net Promoter Score*** is a customer experience metric of loyalty and satisfaction, indicative of demand. NPS is calculated by asking patients the likelihood they would recommend the service on a 0–10 rating scale, and subtracting the percentage of those responding 0-6 from those responding 9-10 to arrive at a cumulative percentage of "promoters" between -100% and 100%.

Patient acceptability is bolstered by evidence-based screening procedures that minimize the need for ultrasound. The intake process screens out patients who do not meet the criteria for teleMAB, such as those with risk factors for ectopic pregnancy. Patients with these risk factors are referred for in-person care or can obtain a pre-treatment ultrasound. However, for the vast majority of cases, an ultrasound for gestational dating or pregnancy location is not required.

Substantial evidence supports gestational age calculation by last menstrual period (LMP) for patients with regular menstrual cycles, as it reduces delays in patient care and financial burdens on both patients and clinics (Schonberg et al., 2014; Raymond & Bracken, 2015; Upadhyay et al., 2022). Accordingly, American College of Obstetricians and Gynecologists (ACOG), National Abortion Federation (NAF), and World Health Organization (WHO) support "no touch" protocols for teleMAB.

Figure 3: Hey Jane patient communication preferences



Source: Hey Jane internal data

Figure 3: 98% of patients preferred an asynchronous method of care, compared to 2% wanting to opt in to a synchronous approach

While most patients do not require in-person care before, during, or after a medication abortion, Hey Jane's teleMAB care model includes guidance for those whose menstrual or medical history requires one. Insured patients are referred to in-network providers, and uninsured patients are encouraged to seek care with a federally qualified health center (FQHC). Ultrasound imaging orders can be sent to free-standing radiology centers, which are often covered by insurance. In the rare instances in which patients have urgent or emergency medical concerns, patients are referred to their closest emergency department. Hey Jane's specialized nursing team ensures the patient has a plan to get there quickly and

safely. Hey Jane's care coordination efforts contribute to its safety profile, as further discussed below.

Intake and prescription

Hey Jane's teleMAB care model begins with a comprehensive questionnaire via asynchronous consult that uses conditional logic to screen out patients who are not appropriate teleMAB candidates. The intake questions are designed to evaluate treatment appropriateness without routine ultrasound using their estimated gestational age (EGA) based on the date of last menstrual period (LMP), menstrual history, and contraindicated risk factors such as ectopic pregnancy risk. A clinician reviews the patient's responses and obtains any necessary clarifications. If necessary based on the patient's history and clinical presentation, they will refer the patient for in-person abortion care or for a pre-treatment ultrasound to confirm intrauterine pregnancy and gestational age. This referral for in-person abortion care or pre-treatment ultrasounds occurs infrequently. Pre-treatment ultrasound results can be securely shared through the HIPAA-compliant patient portal.

After intake has been completed and a licensed and REMS-certified mifepristone prescriber determines the patient is eligible for teleMAB, a physician, nurse practitioner, or nurse midwife will send the medication abortion prescription to a REMS-certified pharmacy. Hey Jane's prescribers can typically complete the process within one business day.

Figure 2: Hey Jane patient experience

Source: Hey Jane internal data

Figure 2: Hey Jane's patient experience consists of an intake form, followed by a consultation with a clinician, delivery of medications to the patient's home via mail, and ongoing educational and community support and content available.

Prescriptions for medication abortion (mifepristone plus misoprostol), pain medication (ibuprofen or acetaminophen), and anti-nausea medication (ondansetron) are sent to a REMS-certified pharmacy that dispenses the medications with a user-friendly 23-page printed treatment guide. The treatment guide contains tips on preparing for treatment, a step-by-step overview of the treatment, what to expect during and after treatment, how to identify and what to do in the event of a medical emergency, and support resources. A digital copy of the guide is also provided.

Patients can reach a clinician via a HIPAA-compliant portal during business hours and via an urgent phone line after business hours. This unlimited clinical support access creates a

patient-centered care environment that meets the needs of diverse patients. Patients receive tailored messages with anticipatory guidance, reminders about medical emergencies, and follow-up instructions to ensure the abortion was complete. .

Asynchronous chat allows patients to connect and talk with a clinician when they need to before, during, and after the abortion. This helps clinicians identify ectopic pregnancy risk early so that at-risk patients are promptly referred out. Through asynchronous chat, Hey Jane clinicians identified eight pre-treatment ectopics in 2022 and three in the first quarter of 2023, even though none of them presented any routine risk factors or flags for ectopic pregnancy at the initial assessment. Of the patients sent for urgent pre-treatment evaluation for suspected atypical ectopic pregnancy, 100% of them were definitively diagnosed with an ectopic pregnancy. Due to the early stage of detection made possible by ongoing asynchronous chat, 90% were managed with methotrexate injection(s), avoiding invasive surgical management that is necessary at greater gestational age.

Post-abortion follow-up

Post-abortion follow-up at Hey Jane uses an evidence-based asynchronous consult sent at 14-day and 28-day intervals post-mifepristone, as well as results from a urine pregnancy test, to determine abortion completion, in accordance with NAF Clinical Policy Guidelines. Patients receive clear instructions on when to conduct a urine pregnancy test and how to identify signs and symptoms that necessitate contacting the clinical team. This approach decreases unnecessary testing or treatment for retained products of conception (rPOC), which is more likely with short-interval follow-up with ultrasonography.

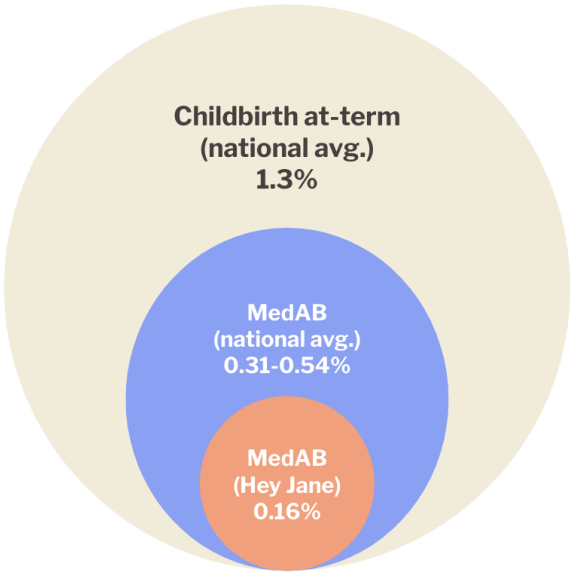
Hey Jane offers high-sensitivity urine pregnancy tests (HSPT) and low-sensitivity urine pregnancy tests (LSPT) as part of the treatment package. Studies indicate that LSPT, along with a series of questions two weeks after medication abortion, can reliably be used to determine the completion of medication abortion. A 2018 systematic review detailed three randomized trials that found no significant difference in the detection of ongoing pregnancy between home LSPT and routine in-person follow-up (Raymond et al., 2018). Multiple adequately powered studies have consistently demonstrated that late presentation at advanced gestational ages due to failure to recognize an ongoing pregnancy is rare when using the LSPT with a questionnaire (Blum et al., 2016; Godfrey et al., 2007; Perriera et al., 2010).

Safety and efficacy

Hey Jane established a robust Continuous Quality Improvement (CQI) program to ensure all patients receive safe, effective, and highly acceptable care. As a leader in the teleMAB field, Hey Jane uses patient clinical safety and quality data to ensure care is of the highest standards and contributes to the growing field of research on teleMAB. In partnership with ANSIRH, Hey Jane can validate internal CQI data externally with congruent results, as further discussed below. Hey Jane has set high standards for internal benchmarks, aiming to have a treatment failure rate of less than 2% and an overall serious adverse event (SAE) rate of less than 0.25%, compared to the 2-5% failure rate and <0.31-0.5% SAE rates commonly reported in medical literature (Pearlman Shapiro et al., 2023; Upadhyay et al., 2022).

Hey Jane's SAE rate in 2022 was 0.16%, compared to the national average in medical literature ranging from 0.31% to 0.54%. SAE levels recently trended even lower at 0.10% for the first quarter of 2023, despite experiencing a 54% increase in volume over the prior quarter. Both Hey Jane and the national risk scores are significantly lower than childbirth at term, which has a 1.3% SAE rate (Figure 4).

Figure 4: Serious adverse event (SAE) rates



Sources: Pearlman Shapiro et al., 2023; Callaghan et al., 2012; Upadhyay et al., 2022

Figure 4: A serious adverse event (SAE) refers to hemorrhage requiring blood transfusion/blood products, hospitalization such as for significant infection, major surgery such as salpingectomy, oophorectomy, and/or hysterectomy, and death.

A common misperception is that abortion is riskier to a person's health than an at-term delivery. However, research has demonstrated that the overall maternal morbidity associated with childbirth at-term exceeds the morbidity associated with abortion (Firoz, et al., 2013), and legal induced abortion is markedly safer than childbirth at-term (Raymond & Grimes, 2012).

Hey Jane has consistently exceeded a 99% success rate with medication abortion treatment failures at <1%, compared to the national average in medical literature of up to 98% (NAF Clinical Policy Guidelines). While the totality of this rate can't be fully accounted for, given individual differences in how patients metabolize medication, there are various contributors to this high efficacy rate, including Hey Jane's high-quality medical protocol, which includes a second dose of misoprostol for EGA >60 days, best-in-class patient education and communication throughout the patient journey, and 24/7 access to specialized clinicians who can answer questions in real time.

CHAT Study and patient population findings

Researchers at ANSIRH conducted the California Home Abortion by Telehealth (CHAT) Study, looking at the safety, effectiveness, and acceptability of teleMAB care, the final results of which are still pending publication.

The CHAT Study partnered with three virtual care providers (including Hey Jane) in 2021 to evaluate the clinical outcomes of teleMAB. CHAT researchers sent surveys to all patients who opted in to the study during the intake process, after taking the medication, and four weeks after the intake visit. Both asynchronous and synchronous teleMAB care models were evaluated. Topics in the surveys included overall telehealth care experience, reasons for choosing telehealth, abortion process, and emotional health.

While safety and acceptability outcomes have not yet been published for CHAT, preliminary analysis indicates that asynchronous teleMAB is very safe and has a high patient acceptability profile. Both of these outcomes are consistent with Hey Jane's internal CQI.

Hey Jane conducted a survey amongst its patient population in the third quarter of 2022 to better understand the reasons that patients were seeking care and the most important factors for choosing services. Survey results from 765 patients show that the most important factor for seeking abortion care with Hey Jane was due to the ability to maintain privacy. The next most important value to patients was convenience of the treatment, followed by speed to care, which is consistent with the preliminary results of the CHAT study.

Conclusion

The asynchronous model for teleMAB provides increased access to abortion care without sacrificing any safety or efficacy as compared with in-person care. The innovative care model is highly acceptable and satisfying to patients, as demonstrated by Hey Jane's NPS score, Hey Jane's internal survey results, and preliminary CHAT Study results. With teleMAB treatments increasing by 395% between 2021 and 2022, the volume of patients seeking abortion via telemedicine at Hey Jane calls for new opportunities for healthcare organizations and payors to meet the demand of their patients and provide them with this service. The time to innovate telemedicine treatment options and asynchronous care methods for increased patient safety, privacy, and access to treatments is now.

The opportunities to include teleMAB as part of organizational reproductive health initiatives and to be responsive to patient demand are more important than ever. Health plans, local and state programs, employers, universities, and other organizations responsible for providing health services must ensure that patients receive equitable care regardless of socioeconomic status, location, and race/ethnicity. As the first fully virtual clinic to accept health insurance for medication abortion, Hey Jane is a pioneer that continues to expand partnerships with key payors. Hey Jane continues to strive to be a leader in the field and is honored to have contributed to a meaningful increase in access to safe, high-quality abortion care during this pivotal time.

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